Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

13010

0 - FRONT

2/24/98

Form Approved OMB No 0910-0291 Expires 12/31/94
See OMB statement on reverse

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTARY reporting by health professionals of adverse events and product problems

CFSAN

Page ___ of ___

FDA Use Only

Triage unit sequence # 860SI

13010

A. Patient information

1 Patient identifier [redacted] In confidence

2 Age at time of event: 34 or Date of birth: [redacted]

3 Sex ☐ female ☒ male

4 Weight ___ lbs or ___ kgs

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e g , defects/malfunctions)

2 Outcomes attributed to adverse event (check all that apply)

☐ death ___ (mo/day/yr)
☐ life-threatening
☐ hospitalization – initial or prolonged
☐ disability
☐ congenital anomaly
☒ required intervention to prevent permanent impairment/damage
☐ other

3 Date of event (mo/day/yr) 11.23.97

4 Date of this report (mo/day/yr) 2.24.98

5 Describe event or problem

Patient in chronic use of medication, developed disorientation, abdominal pain with burning, anorexia with weight loss.
He developed headaches following abrupt discontinuation of the medication — A mild depression & anxiety also was noted.

6 Relevant tests/laboratory data, including dates

Gastroscopy on 1.10.98 —
Hiatal hernia,
Antral gastritis with erosions.
Duodenitis.

7 Other relevant history, including preexisting medical conditions (e g , allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc)

REC'D.
JUN 0 7 1998
MEDWATCH CTU

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REVIEW/OSN HFS-452
'98 JUL 21 A7:53

C. Suspect medication(s)

1 Name (give labeled strength & mfr/labeler, if known)
#1 Ripped Fuel (Twin Lab)
#2

2 Dose, frequency & route used
#1 4-6 cap en day
#2

3 Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 6 months - starting 6-97
#2

4 Diagnosis for use (indication)
#1 Promote Wt. Muscle Strength
#2

5 Event abated after use stopped or dose reduced
#1 ☒ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

6 Lot # (if known)
#1 27434 07077.
#2

7 Exp. date (if known)
#1
#2

8 Event reappeared after reintroduction
#1 ☐ yes ☐ no ☒ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

9 NDC # (for product problems only)

10 Concomitant medical products and therapy dates (exclude treatment of event)

None.

D. Suspect medical device

1 Brand name

2 Type of device

3. Manufacturer name & address

4 Operator of device
☐ health professional
☐ lay user/patient
☐ other

5 Expiration date (mo/day/yr)

6
model #
catalog #
serial #
lot #
other #

7. If implanted, give date (mo/day/yr)

8 If explanted, give date (mo/day/yr)

9 Device available for evaluation? (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on ___ (mo/day/yr)

10 Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone #
[redacted]

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2 Health professional? ☒ yes ☐ no

3 Occupation

4 Also reported to
☐ manufacturer
☐ user facility
☐ distributor

5 If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. ☐

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to: 1-800-FDA-0178

FDA Form 3500 (6/93)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

860SI

ADVICE ABOUT VOLUNTARY REPORTING

Report experiences with:

- medications (drugs or biologics)
- medical devices (including in-vitro diagnostics)
- special nutritional products (dietary supplements, medical foods, infant formulas)
- other products regulated by FDA

Report SERIOUS adverse events. An event is serious when the patient outcome is:

- death
- life-threatening (real risk of dying)
- hospitalization (initial or prolonged)
- disability (significant, persistent or permanent)
- congenital anomaly
- required intervention to prevent permanent impairment or damage

Report even if:

- you're not certain the product caused the event
- you don't have all the details

Report product problems – quality, performance or safety concerns such as:

- suspected contamination
- questionable stability
- defective components
- poor packaging or labeling

How to report:

- just fill in the sections that apply to your report
- use section C for all products except medical devices
- attach additional blank pages if needed
- use a separate form for each patient
- report either to FDA or the manufacturer (or both)

Important numbers:

- 1-800-FDA-0178 to FAX report
- 1-800-FDA-7737 to report by modem
- 1-800-FDA-1088 for more information or to report quality problems
- 1-800-822-7967 for a VAERS form for vaccines

If your report involves a serious adverse event with a device and it occurred in a facility outside a doctor's office, that facility may be legally required to report to FDA and/or the manufacturer. Please notify the person in that facility who would handle such reporting.

Confidentiality: The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. The reporter's identity may be shared with the manufacturer unless requested otherwise. However, FDA will not disclose the reporter's identity in response to a request from the public, pursuant to the Freedom of Information Act.

FDA Form 3500-back **Please Use Address Provided Below – Just Fold In Thirds, Tape and Mail**

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Rockville, MD 20857

Official Business
Penalty for Private Use $300

NO POSTAGE NECESSARY IF MAILED IN THE UNITED STATES OR APO/FPO

BUSINESS REPLY MAIL
FIRST CLASS MAIL PERMIT NO. 946 ROCKVILLE, MD

POSTAGE WILL BE PAID BY FOOD AND DRUG ADMINISTRATION

MEDWATCH
The FDA Medical Products Reporting Program
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20852-9787

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CLINICAL RESEARCH
& REVIEW/OSN HFS-452

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COMPLAINT/INJURY REPORT

1. COMPLAINT NUMBER: CHI-6130

2. DATE OF COMPLAINT (Month/Day/Year): 07/23/98

3. FORM OF COMPLAINT
(1) ☐ TELEPHONE
(2) ☒ LETTER
(3) ☐ VISIT

4. SOURCE OF COMPLAINT
(1) ☐ CONSUMER
(2) ☐ GOVERNMENT ☐L ☐S ☐F
(3) ☒ TRADE SOURCE
(4) ☐ OTHER (Indicate in Remarks)

5. COMPLAINANT IDENTIFICATION
a. NAME AND ADDRESS (Include ZIP Code): [redacted]
b. AREA CODE AND TELEPHONE NUMBER
HOME ( )
WORK [redacted]

6. COMPLAINT OR INJURY
a. DESCRIPTION OF COMPLAINT/INJURY
The complainant stated that a 34 yr. old male patient, [redacted] developed abdominal pain with burning, anorexia with weight loss and disorientation after using the product for six months. After discontinuing the product he developed headaches, mild depression and anxiety. A gastroscopy on 1/10/98 revealed a hiatal hernia, antro fascitis with erosions and duodenitis.

b. DOES COMPLAINANT EXPECT ADDITIONAL FDA CONTACT?
(1) ☒ NO (2) ☐ YES (Explain in Remarks)

7. INJURY OR ILLNESS RESULTED
(1) ☐ NO
(2) ☒ YES
(If "yes" complete items a through d)

a. EIB (HFC-161) NOTIFIED
(1) ☒ NO
(2) ☐ YES
DATE

b. TYPE SYMPTOMS — ONSET (HR.)
1. ☐ VOMITING
2. ☐ NAUSEA
3. ☐ DIARRHEA
4. ☐ FEVER
5. ☐ SKIN/EYE IRR.
6. ☒ HEADACHE
7. ☒ OTHER
see #6

c. ATTENDING HEALTH PROFESSIONAL
(1) ☐ NO (2) ☒ YES
(If "yes" give name, address, and phone number)
[redacted]

d. HOSPITALIZATION REQUIRED
(1) ☒ NO (2) ☐ YES
(If "yes" give name, address, phone number and cause)

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8. PRODUCT AND LABELING
a. BRAND NAME: Twinlab Ripped Fuel
b. PRODUCT NAME: Ma Huang/Guarana/L-Carnitine/Chromium Picolinate
c. SIZE AND PACKAGE TYPE: capsule bottle
d. NAME AND LOCATION OF STORE WHERE PURCHASED: ~~not known~~ [redacted]
e. PACKAGE CODE/SERIAL NUMBER/ETC.: 27434-07077 (UPC??)
EXP/USE BY DATE:
f. DATE PURCHASED: JUN/DEC 97
g. PRODUCT USED (If "yes" enter date) JUN/DEC 97 (1) ☐ NO (2) ☒ YES
h. AMT REMAINING: not known

9. MANUFACTURER/ DISTRIBUTOR OF PRODUCT
a. HOME DISTRICT: NYK-DO
b. C.F. NO.: 2421049
c. NAME AND LOCATION OF FIRM (Include ZIP Code):
Twin Labs Inc.
2120 Smithtown Ave.
Ronkonkoma, NY 11779
d. IMPORT PRODUCT
(1) ☒ NO
(2) ☐ YES

10. EVALUATION AND DISPOSITION
a. PROBLEM KEYWORD
(1) CODE: RX
(2) DESCRIPTION: abdominal pain

b. EVALUATION
(1) ☐ NOT AN FDA OBLIGATION
(2) ☐ OBLIGATION, NO VIOLATION
(3) ☒ FDA ACTION INDICATED
(4) ☐ INSUFFICIENT INFORMATION UNABLE TO EVALUATE

c. DISPOSITION
(1) ☒ IMMEDIATE FOLLOW-UP
(2) ☐ F/U NEXT EI
(3) ☐ CLOSED WITHOUT FURTHER INVESTIGATION
(4) ☐ REFERRED TO OTHER FEDERAL AGENCY (Closes File)
(5) ☐ REFERRED TO STATE/LOCAL AGENCY (Closes file)
(6) ☐ REFERRED TO OTHER FDA_____ DISTRICT
(7) ☐ REFERRED TO OCI

11. PRODUCT CODE: 54FCE09

12. INFORMATION COPIES TO:
☐ HFB-100 ☐ HFZ-343
☐ HFD-730 ☒ HFC-161
☐ HFV-236 ☒ HFS-635

REMARKS
CFSAN Project #13010

NAME AND TITLE: Kathleen E. Haas, CCC

DATE: 07/23/98

000003

FORM FDA 2516 (5/94)

[redacted]: Assign Food team
[illegible] 8-24-98
[redacted]

COMPLAINT/INJURY FOLLOW-UP

1. COMPLAINT NUMBER CHI-6130

2. ACTION REQUESTED
- (1) ☒ INVESTIGATION
- (2) ☐ COLLECT SAMPLE
- (3) ☐ INSPECTION
- (4) ☐ OTHER

(a) REMARKS (Additional Details)
Visit the doctor to obtain the patient's name & address to obtain a medical release, adverse event questionnaire info, copy of product label. Revisit doctor and obtain copies of medical records. Verify which formula of Ripped Fuel was used.

(b) REQUESTING OFFICIAL'S NAME AND TITLE	(c) DATE REQUESTED	(d) PRODUCT NAME
Kathleen E. Haas, CCC	07/23/98	Ripped Fuel Capsules

3. ASSIGNED TO:	(a) DUE BY	4. ACTION TAKEN	(a) SAMPLE NUMBER(s)
JAMES T. KARPUS	08/24/98	(1) ☒ INVESTIGATION (2) ☐ SAMPLE COLLECTED (3) ☐ INSPECTION (4) ☐ NONE	N/A

(b) DESCRIPTION OF ACTION TAKEN

On 8-17-98, I obtained the name, address and home/business phone numbers of the patient/consumer, [redacted] from the doctor's assistant by phone, after their clinical records department was unable to locate the patient's file for several days.

On 8-21-98, after a multi-day span during which I made several phone calls to, and left several voice-mail messages for, Mr. [redacted] at both his residence and his place of business, he agreed to meet me after work hours at a restaurant local to his [redacted] home.

At our meeting, Mr. [redacted] indicated that he had purchased the subject product, TWINLAB METABOLIC ENHANCER RIPPED FUEL, through a mail-order supply house, [redacted] (See FDA 2516 for container code. See Adverse Event Questionnaire for product formula verification.) He further stated that he had used the product in conformity with label directions, namely at a beginning dosage of 4 capsules/day, which he subsequently increased to 6 capsules/day. Concomitant treatments included daily usage of other dietary supplements, including amino acids, chromium picolinate, creatine and L-carnitine. The subject product was always taken with water, and was taken at home and/or at work.

In describing his illness, the onset of which occurred 6 months after daily product usage, Mr. [redacted] said it began with stomach pain and disorientation while driving home late

(CONTINUED)

(c) ACTION OFFICIAL'S NAME AND TITLE	(d) ACTION DISTRICT	(e) DATE COMPLETED
James T. Karpus, CSO *James T. Karpus*	CHI	8-24-98

5. MANUFACTURER/DISTRIBUTOR/DEALER RESPONSIBLE

(a) HOME DIST.	(b) CF NO.	(c) NAME AND ADDRESS
NYK	2421049	Twin Labs Inc. 2120 Smithtown Ave. Ronkonkoma, NY 11779

6. PROGRAM DATA

(a) OPERATION	(b) PAC	(c) PRODUCT CODE	(d) EMP. HOME DIST.	(e) EMP. NO.	(f) POS CL.	(g) HOURS
13	03R801	54FCE09	CHI	767	2	21

7. EVALUATION
- (0) ☐ PENDING
- (1) ☒ NO ACTION INDICATED (NAI)
- (2) ☐ VOLUNTARY ACTION INDICATED (VAI)
- (3) ☐ OFFICIAL ACTION INDICATED (OAI)
- (4) ☐ NOT AN FDA OBLIGATION
- (5) ☐ REFERRED TO HOME DISTRICT
- (6) ☐ INSUFFICIENT INFO. UNABLE TO EVAL.

8. FINAL DISPOSITION
- (1) ☐ FOLLOW-UP NEXT E I
- (2) ☐ WARNING LETTER
- (3) ☐ CITATION
- (4) ☐ SEIZURE
- (5) ☐ INJUNCTION/PROSECUTION
- (6) ☐ REFERRED TO OTHER AGENCY (Indicate Agency in Remarks)
- (7) ☐ RECALL
- (8) ☒ NO ACTION

9. INFO. COPIES TO
- ☐ HFB-100
- ☐ HFD-730
- ☐ HFV-236
- ☐ HFZ-343
- ☒ HFC-161
- ☒ HFS-635
- NYK-DO

REMARKS

NAME AND TITLE OF DISPOSITION OFFICIAL	DISPOSITION	DISPOSITION DATE
Kathleen E. Haas, CCC	CHI	8/27/98

000004

FORM FDA 2516a (1/90)

FDA FORM 2516a, Item 4(b) continued

one night about 5 hours after having a restaurant dinner that included shrimp, roast beef, chicken breast, cooked veggies, soup, 3 glasses of wine, and 2 drinks of vodka with soda. (Lunch that day had consisted of a tuna salad sandwich.) The illness continued 3-4 days, during which he also experienced loss of appetite and of weight. On about Day 4, he visited Dr. [redacted] of [redacted] who diagnosed a hiatal hernia, antral gastritis with erosions, and duodenitis, and who prescribed medication. (See attached records.) In regard to his visit to the doctor, Mr. [redacted] mentioned that despite the medication and his no longer taking RIPPED FUEL, he remained ill for 3-4 weeks. This latter period was characterized by headaches, nausea, anorexia, mild depression and anxiety. Mr. [redacted] related that his illness cleared up at the end of this period.

In responding to questions regarding his medical history, Mr. [redacted] stated, for the record, that he has no pre-existing conditions, no high blood pressure, no particular health problems (no chronic disease and no historic acute episodes), and claims he is in good health, other than being slightly overweight.

After my interview, Mr. [redacted] thanked me for my time, and for the government's interest in doing a follow-up.

I did not collect a sample, and concluded my investigation. (See attachment for product labeling.)

In an interview of the physician conducted by myself on 8-24-98, Dr. [redacted] indicated that while he felt his intervention was probably not required to prevent permanent injury/damage, he was nevertheless convinced that Mr. [redacted] long-term ingestion of RIPPED FUEL was a factor in his illness. He further stated that he had no particular clinical experience with the herb, ma huang (ephedra), and did not recall treating any patients who described taking the herb.

Adverse Event Questionnaire

Complaint Number: CHI-6130 **Investigator:** JAMES T. KARPUS

Consumer Information

Date of Report: 08/21/98 (MM/DD/YY)

Initial Report Source: ☐ORA Consumer Injury ☐Telephone ☐Correspondence ☒MedWatch ☐USP ☐PQRS ☐Poison Control ☐CDC

Name: [redacted] Gender: ☐F ☒M Age: 35

Race: ☒1-White ☐2-Black ☐3-Asian/Pacific Islander ☐4-Native American ☐5-Hispanic ☐8-Other_____ ☐9-Unknown

Information on Adverse Event

Date of Adverse Event: 11/23/97
Previous Adverse Effects to Product Type: ☐Yes ☒No

Give the site of consumption/ingestion (e.g. home, restaurant, office): HOME & OFFICE

The following information relates to the consumers' use of the product.

Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms): AFTER 6 MONTHS OF PRIOR USE, CONSUMER DEVELOPED STOMACH UPSET, DISORIENTATION ("WACKED OUT OF MY GOURD") & LOSS OF APPETITE. CONSUMER WAS UNABLE TO GO TO WORK [*1] LIVED ON H_2O & ANTACIDS & LOST WEIGHT
How long did the symptoms last? 3 TO 4 DAYS UNTIL VISIT TO PHYSICIAN [*2] [*1] (FOR 3-4 DAYS)
Give the circumstances of exposure (i.e. how much was taken, how was the product taken, how often was it taken, etc.). DOSAGE WAS INITIALLY 4 CAPS/DAY, WAS INCREASED TO 6 CAPS/DAY AFTER CONSUMER "BUILT UP RESISTANCE". CAPS WERE TAKEN BEFORE MEALS, AND/OR THROUGHOUT DAY, WITH WATER.

List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used at the time of the event: MEDS: NONE DS: CREATINE, CARNITINE, AMINO ACIDS, CHROMIUM PICOLINATE. FOODS/DRINK: SHRIMP, CHICKEN, ROAST BEEF, VEGGIES, SALSA, 3 GLASSES WINE, 2 VODKA &
Did event abate after use of suspected product stopped or dose reduced: ☐Yes ☒No ☐Unknown
Did symptoms reoccur after reintroduction of suspected product: ☐Yes ☐No ☐Unknown ☒Not Applicable
Did symptoms reoccur after using other products with the same ingredients: ☐Yes ☐No ☐Unknown ☒Not Applicable

Medical Information

Was a health care provider seen?: ☒Yes ☐No
Give health care provider's name, address and telephone number: [redacted] MD, [redacted]

Occupation of Health Care Provider: ☒MD ☐Osteopath ☐Naturopath ☐Nurse ☐Pharmacist ☐Other (specify) _____

What medical tests were performed and what were the results? A GASTROSCOPY & A BIOPSY. THE BIOPSY WAS NEGATIVE FOR HELICOBACTER PYLORI. FROM GASTROSCOPY:
What was the medical diagnosis? HIATAL HERNIA, ANTRAL GASTRITIS WITH EROSIONS, DUODENITIS.
What treatment(s) was given (e.g., drugs, other)? RANITIDINE, PREVACID

Were there any preexisting condition(s)/treatment(s)? (If YES, list them including allergies, and chronic diseases): ☐Yes ☒No

[*2] AFTER VISIT TO PHYSICIAN, CONSUMER WAS ILL 3-4 WEEKS WITH HEADACHES, NAUSEA, ANOREXIA, MILD DEPRESSION & ANXIETY.

Product Category

1. Adverse event attributed to:
   ☐**Medical Food** (under medical supervision) ☐**Infant Formula**
   ☒**Dietary Supplement** (a vitamin; an essential mineral; a protein; a herb or similar nutritional substances including botanicals such as ginseng and yohimbe; amino acids; extracts from animal glands; garlic extract; fish oils; oil of evening primrose; fibers such as psyllium and guar gum; compounds not generally recognized as food or nutrients, such as bioflavonoids, enzymes, germanium, nucleic acids, para-amino-benzoic acid, and rutin; and mixtures of these ingredients.)
   ☐**Other** (traditional food) _____

Other Product Problems

2. ☐Foreign Object
(specify):_____

3. ☐Other (specify):
_____

Information on Suspected/Alleged Product

Give the product name and manufacturer as listed on the label (including the recommended dosage/serving size, recommended duration of use, and indications for use as listed on the label): METABOLIC ENHANCER RIPPED FUEL MFGR: TWIN LABORATORIES INC, RONKONKOMA, NY 11779. USE: TAKE 2 CAPS BEFORE MORNING WORKOUT ON AN EMPTY STOMACH. ALSO, TAKE 2 CAPS BEFORE AFTERNOON & EVENING MEALS. DO NOT EXCEED 6 CAPS DAILY. TAKING MORE THAN THE RECOMMENDED AMOUNT WILL NOT IMPROVE RESULTS AND MAY CAUSE ADVERSE REACTIONS LISTED IN THE WARNING BELOW BEGIN USE WITH ½ RECOMMENDED DOSE (1 CAP 3 TIMES/DAY) TO ASSESS YOUR TOLERANCE. IMPROPER USE MAY BE HAZARDOUS TO A PERSON'S HEALTH

List product ingredients (if ingredients are suspected to be present, but not verified, list as suspected):
☐Check here if ingredients are unknown
(1) MA HUANG EXTRACT (2) GUARANA EXTRACT (3) L-CARNITINE (4) CHROMIUM (FROM CHROMIUM PICOLINATE) OF RIPPED FUEL. THIS IS THE VERIFIED PRODUCT/FORMULA USED BY CONSUMER. 2 OTHER PRODUCT FORMULAS EXIST: 1ST OF 2 CONTAINS PHENYLALANINE AS DISTINCTIVE INGREDIENT; 2ND OF 2 CONTAINS DHEA & YOHIMBE BARK EXTRACT AS DISTINCTIVE INGREDIENTS.

If a particular ingredient is suspected of contributing to the adverse event, please indicate the appropriate category below:

☐Aspartame
☐Monosodium Glutamate
☐Sulfite
☒Other MA HUANG
☐Unknown

☐Color Additive (please specify) _____

Is the product label available, if yes submit a quality copy along with this questionnaire: ☒Yes ☐No
☐Unknown Product Sample Available: ☐Yes ☐No ☒Unknown SOLITARY CONSUMER JAR LEFT LABEL-INTACT. SEE ATTACHMENT FOR WRITTEN LABEL REPRODUCTION VERIFIED AS ACCURATE BY CONSUMER.

Outcome Attributed to Adverse Event:
(If yes, include pertinent medical records)

Death: ☐Yes ☒No

Life-Threatening: ☐Yes ☒No

Hospitalization: ☐Yes ☒No (if YES, indicate if initial or prolonged) _____

Required intervention to prevent permanent impairment/damage: ☐Yes ☒No

Did the adverse event result in a congenital anomaly: ☐Yes ☒No